REMARKS

1. Status of the Claims

Claims 1-15 are pending. Claims 1-12 are being examined and claims 13-15 have been withdrawn. Applicants thank the Examiner for withdrawing the election of species requirement.

2. Amendments to the Specification

Applicants provide a substitute Abstract, starting on a separate page.

3. Rejections Under 35 U.S.C. § 101

The Examiner rejects claims 1-12 under 35 U.S.C. § 101 as directed to non-statutory subject matter. Applicants respectfully traverse.

a. Measurement and determination steps encompass statutory subject matter under 35 U.S.C. § 101.

The Supreme Court has construed §101 broadly, noting that Congress intended statutory subject matter to "include anything under the sun that is made by man." *Diamond v. Chakrabarty,* 447 U.S. 303, 309, 206 U.S.P.Q. 193 (1980). There are some exceptions. "Laws of nature, natural phenomena, and abstract ideas" are excluded from patentability. *Diamond v. Diehr,* 450 U.S. 175, 185, 209 U.S.P.Q. 1 (1981). However, an *application* of a law of nature, natural phenomenon, or abstract idea is patentable. *Id.*

In re Bilski, 545 F.3d 943, 953, 88 U.S.P.Q.2d 1385 (Fed. Cir. 2008) (*en banc*), cert. granted, 129 S. Ct. 2735 (June 1, 2009), articulated the test for whether a process is patentable: "A claimed process is surely patent-eligible under §101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing." *Id.*

In addition the machine or transformation cannot be "insignificant extra-solution or activity" and must be "central to the purpose of the claimed process." *Prometheus Laboratories v. Mayo Collaborative Services,* 92 U.S.P.Q.2d 1075, 1083 (Fed. Cir. 2009)(quoting *Bilski*). The machine or transformation must also "impose meaningful limits on the claim's scope." *Id.*

Prometheus Laboratories interpreted the *Bilski* test in the field of biotechnology, finding that claims to administering a drug and detecting its level were patentable. The court specifically held that determining the drug's level in serum imparted patentability:

> Determining the levels of 6-TG or 6-MMP in a subject necessarily involves a transformation, for those levels cannot be determined by mere inspection. Some form of manipulation . . . is necessary to extract the metabolites from a bodily sample and determine their concentration. As stated by Prometheus's expert, "at the end of the process, the human blood sample is no longer human blood; human tissue is no longer human tissue." That is clearly a transformation.

Prometheus Laboratories, 92 U.S.P.Q.2d at 1083. (Internal Citations Omitted).

Further, the "determining" step was held <u>not</u> to be mere data-gathering because "[m]easuring the levels of 6-TG and 6-MMP is what enables possible adjustments to thiopurine drug dosage to be detected for optimizing efficacy or reducing toxicity during a course of treatment. The determining step, by working a chemical and physical transformation on physical substances, likewise sufficiently confines the patent monopoly, as required by *Bilski.*" *Id.*

When viewing the methods as a whole, a therapeutic method to determine a "course of treatment" is still patentable even when a drug's dose is not adjusted. *Id.* at 1084.

b. The claimed invention qualifies as patentable subject-matter under the machine-or-transformation test.

Applicants submit that claims 1-12 encompass patentable subject matter. Like the determination of the drug's level in *Prometheus Laboratories*, claim 1 encompasses a transformation of the sample through the measurement of pepsinogen I and Gastrin-17 and the determination of the presence of a *H. pylori* marker. During that measurement and determination, the sample, (*i.e.* a body fluid) is transformed through a chemical process. (See Specification page 4, line 30 to page 5, line 2).

Furthermore, the measurement and determination step is <u>not</u> merely "data-gathering" as that information is *central to* and *enables* the classification of the status of the gastric mucosa. That status is then "used to generate a diagnosis or a suggestion for treatment or further

investigation and/or tests." (Specification, page 11, lines 20-21). Such a diagnosis can include gastric cancer, peptic ulcers, or *H. pylori* infection and related conditions. (Specification, Examples and page 2, line 17 to page 3, line 27). The measurement of PGI and G-17 and determination of the presence of a *H. pylori* marker.

Even if no other action is taken after the measurement and determination steps, the "course of treatment" of the gastric mucosa can include inaction, as discussed in *Prometheus Laboratories*.

Accordingly, Applicants submit that claims 1-12 encompass statutory subject matter. Applicants request that the rejection be withdrawn.

4. **Rejection Under 35 U.S.C. § 103**

The Examiner rejects claims 1-12 under 35 U.S.C. § 103 as unpatentable over Väänänen et al. or Suovaniemi (U.S. 2004/003837) in view of García-Fernández et al. and Ashton et al. (U.S. 6,950,544). Applicants respectfully traverse.

Applicants herein provide the Declaration of Dr. Sarna. In the Declaration Dr. Sarna compares the method of the claimed invention to the methods of Väänänen or Suovaniemi in view of García-Fernández and Ashton et al. Dr. Sarna concludes that one of skill in the art would not have found the present invention obvious based on the four references because the present invention applies the "Path model", a multinomial regression which results in probabilities of the certainty of the classification of the status of the gastric mucosa, and diagnosis of the subject.

Dr. Sarna also concludes that the addition of Ashton and García-Fernández does not make the determination of the probabilities for the gastric mucosa to belong to atrophic gastritis obvious. Specifically, the references apply an algorithm for a different disease with a different statistical method (Ashton uses maximum likelihood estimation), and with a different model (i.e.,

classification of MRI imaging data in Ashton as opposed to the Path Model of the claimed invention).

Accordingly, Applicants submit that one of skill in the art would not have found the present invention obvious over Väänänen et al. or Suovaniemi in view of García-Fernández et al. and Ashton et al. Applicants request that the rejection be withdrawn.

5. Rejection under Obviousness-Type Double-Patenting

It is unclear which claims the Examiner rejects under the judicially created doctrine of obviousness type double patenting. The claims recited on page 10 of the Office Action do not correspond to the pending claims.

That said, Applicants submit that the pending claims 1-12 are not unpatentable over claims 1-26 of U.S. Patent 7,358,062 (the patent maturing from the application in U.S. Publication Number 2004/003837, cited above) in view of García-Fernández et al. and Ashton et al. (U.S. 6,950,544) for the reasons discussed above. Applicants request that the rejection be withdrawn.

Conclusion

An early and favorable first action on the merits is earnestly solicited.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson (Reg. No. 30,330) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a two (2) month extension of time for filing a reply in connection with the present application, and the required fee of $245.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

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Attachments: Declaration of Dr. Sarna
Abstract